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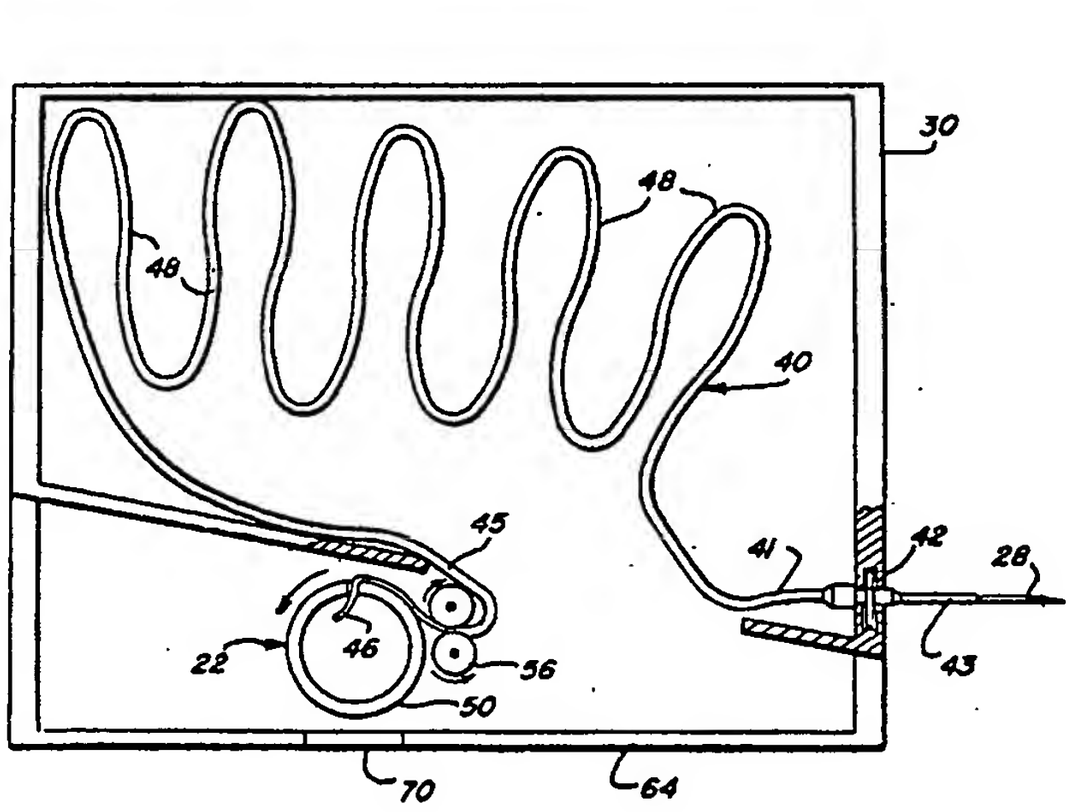
(57) Abstract

A wearable infusion system for delivering a fluid medication such as insulin to a patient through a needle, cannula or catheter (28). The infusion system includes a medication-filled elongate, thin-walled tubular reservoir (40) and a positive displacement metering assembly (22) operated by a power source under the control of a controller such as a microprocessor (24). The positive displacement metering assembly (22) draws the reservoir (40) inwardly between squeeze surfaces (56) which forces the medication toward the remote end where it discharges through an associated cannula, catheter or needle (28) into a patient. The rate and frequency at which the metering assembly is operated controls the rate and frequency at which the medication is delivered to the patient. The tubular reservoir defines a plurality of loops (48) so that a maximum amount of fluid medication may be disposed in a housing.



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# WEARABLE INSULIN INFUSION SYSTEM HAVING A TUBULAR RESERVOIR AND A POSITIVE DISPLACEMENT METERING MEANS

## Background of the Invention

This invention relates to wearable infusion systems for delivery of fluid medications, and especially to one which is suitable for the infusion of insulin.

Considerable research has been directed to improving systems for administering insulin, a pancreatic hormone, to patients whose own body does not adequately or properly respond to shifting blood-sugar levels. Whereas a properly functioning pancreas will automatically respond to changes in blood-sugar level to produce and release the necessary insulin, the pancreas of a person such as a diabetic does not do so. Therefore, the administration of insulin from an external source to such persons is necessary.

Insulin deficiency is treated in a variety of ways, depending on the patient. Oral medication can be taken by some diabetics. Daily insulin injections can be taken by others. Here again, although injections may correct a quantitative deficiency, they do not provide insulin at the specific times when it is needed, and, accordingly, such patients' blood-sugar levels may fluctuate widely during the day. Such patients must constantly be on the alert for abnormalties in blood-sugar levels and must have sugar and extra doses of insulin available to them for use when necessary to avoid extreme reactions, such as diabetic comas and the like.

For some, these available possibilities are not adequate or satisfactory, and it has been recognized for some time now that an artificial pancreas

would be highly desirable. Efforts to produce an artificial pancreas, one which will release insulin on demand as would a properly functioning pancreas, have been made. For example, minature battery-powered pumps which continuously trickle insulin into the body have been designed and attempts have been made to design devices which automatically and continuously measure blood-sugar levels so that insulin can be infused "on demand." Some such systems have been designed for implantation and others have been designed for wearing externally, as on a belt or in a shoulder bag or the like.

Of course, all systems for continuous or continual infusion of insulin into the body present difficulties and problems. Typical difficulties encountered relate to the designing of blood-sugar sensing devices which are specific to blood-sugar, which are reliable over long periods when in contact with body fluids, and which are sufficiently compact, the development of implantable catheters which are usable for prolonged periods without failure or promoting infection, and the development of delivery and dispensing systems for insulin which are reliable, accurate, simple and compact. Of course, any delivery and dispensing system requires replenishment of the insulin supply periodically and therefore any associated reservoir must provide ready access thereto for refilling or replacement.

It is an objective of the present invention to provide an improved delivery and dispensing system including a replaceable reservoir for continuously or continually infusing insulin into a human body at a selected basal or an accelerated "bolus" rate.

Summary of the Invention

In accordance with the present invention, an infusion system for controllably and positively delivering a drug such as insulin in fluid form at selected rates for discharge into a human body is provided. The insulin may be infused continuously or intermittently and subcutaneously, intraperitoneally or into an artery or vein, and may be done automatically. The present system also permits the patient to elect to have an augmented or additional infusion (bolus) as required at a rate or rates determined in advance by the prescribing physician or based upon the patient's assessment of the sugar content of his next meal.

The present system includes an elongate, continuous, thin-walled replaceable tubular reservoir and a positive displacement metering assembly. The metering assembly is operated by a power source that can be controlled by a suitable microprocessor. The reservoir, metering assembly, power source and microprocessor or like control device are adapted to be worn by a patient as on his belt, in a shoulder bag or by strapping to an extremity or his torso.

The discharge from the reservoir is positively metered for infusion into a patient, such as through an associated needle terminated cannula or implanted catheter, as desired. When the insulin supply becomes exhausted, the reservoir and metering assembly are easily removed and replaced, and in minutes the system is ready to continue the infusion of insulin.

In a preferred embodiment the tubular reservoir is housed in a replaceable cartridge comprising an enclosure and has a first end portion terminating in a connector segment adapted to be placed in fluid

communication with a catheter, cannula, needle or other means for infusing medication into the patient. The connector segment is suitably secured to the enclosure. The other end portion of the tubular reservoir is adapted to be secured to a positive displacement metering assembly which may comprise squeeze surfaces and a take-up spool or shaft. As the metering assembly is driven, the second end portion moves in a direction to reduce the effective length of the reservoir. As the reservoir is so moved, the squeeze surfaces, which preferably are a pair of closely spaced squeeze rollers, compress and flatten the reservoir, forcing the insulin towards the connector. The take-up spool wraps the flattened reservoir portion therearound. The flattening of the reservoir and the attendant dispensing of reservoir contents at predetermined rates, as determined by the microprocessor or other control means, thereby serves to meter and control the rate of discharge of medication through the connector segment, thence through the catheter, cannula or needle.

The tubular reservoir preferably defines a plurality of loops between the end portions. The loops may be generally circular and disposed in a spiral or helical coil configuration in plan view or may be zig-zag or finger-like in configuration. The loops may be arrayed in a plane or may be arrayed in stacks. The configurations are selected to provide for the maximum volume of fluid to be dispensed from an enclosure of minimal size, preferably so that at least a week's supply may be provided in the replaceable supply unit.

The metering assembly may have a driven take-up spool, driven squeeze rollers or both to

insure positive displacement of the medication, e.g., insulin, and at a constant or variable predetermined rate or rates.

Brief Description of the Drawings

FIGURE 1 is a partly schematic view of a wearable insulin infusion system according to the present invention, including a tubular reservoir having a connector for communicating the reservoir with a human body, and a powered positive displacement metering assembly under the control of a suitable controller;

FIGURE 2 is an enlarged plan view of the tubular reservoir and positive displacement metering assembly of FIGURE 1;

FIGURE 3 is a fragmentary perspective view of the positive displacement metering assembly of FIGURE 2;

FIGURE 4 is a side elevational view of the positive displacement metering assembly of FIGURE 2;

FIGURE 5 is a plan schematic view of a further embodiment of a tubular reservoir and metering assembly of this invention;

FIGURE 6 is a plan view of a further embodiment of a tubular reservoir and metering assembly of this invention;

FIGURE 7 is a side elevational view of FIGURE 6;

FIGURE 8 is a fragmentary plan view of another embodiment of a metering assembly of this invention;

FIGURE 9 is a cross-sectional view of a further tubular reservoir in accordance with this invention;

FIGURE 10 is a perspective view of a further embodiment of a metering assembly of this invention; and

FIGURE 11 is a fragmentary plan view of a further tubular reservoir embodiment of this invention.

Detailed Description of the Preferred Embodiments

Referring to the drawings and particularly to FIGURE 1, a wearable system 10 for controllably delivering fluid medication, such as insulin, at selected rates for discharge into a human body in accordance with this invention is seen to include a replaceable supply reservoir 20, a positive displacement metering assembly 22 adapted to be controlled by a controller such as a microprocessor 24 and a power source 26 for operating the metering assembly in response to a control signal from microprocessor 24. The supply reservoir 20 provides a connector which is adapted to be placed in fluid communication with an infusion means, such as a needle 28, for discharging the fluid from the supply reservoir 20 into a human body. Needle 28 may be covered with a suitable sterile shield which may be removed before use.

Although it is not shown in FIGURE 1, the supply reservoir 20, positive displacement metering assembly 22, microprocessor 24 and power source 26 may be assembled in a compact, wearable pack adapted to be worn by the patient, such as by being strapped to the body or positioned on a belt or in a shoulder pack. Alternatively, portions of the system 10 may be secured to the torso and other body portions, or worn in a shoulder pack or the like.

The supply reservoir 20, as seen in FIGURE 2, may comprise a removable or replaceable cartridge including enclosure 30 housing a fluid reservoir 40. Reservoir 40 is an elongate, continuous, readily flattenable, thin-walled tube which is circular in cross-section and is made of a sterile, sanitary

material such as biaxially oriented polyethylene terephthalate. It is dimensionally stable, non-stretchable and is readily flattenable and collapsible from its circular cross-sectional configuration. Polyethylene and polyurethane tubing may also be considered for use. Tubular reservoir 40 terminates at a first end in a first end portion 41 which has a connector segment 42. Connector segment 42 is suitably anchored or secured to enclosure 30 so that it will not pull out or move with respect to the enclosure, as illustrated by FIGURE 2. Connector segment 42 is adapted to be secured, as removably secured, to an infusion means, such as a four to six inch long tubular cannula segment 43 terminating in a needle 28 for subcutaneous infusion, as in a manner to be described. The reservoir 40 may terminate in a connector segment integral therewith or assembled thereto. Similarly, the cannula segment 43 may be an integral extension of the reservoir 40 and/or the connector segment or may be separate therefrom and assembled thereto to provide an integrated connector means for securance to the needle or implanted catheter, i.e., a suitable infusion means, and to the enclosure.

The second end portion 45 preferably terminates in a sealed, flattened, tape-like segment 46 adapted to be secured to metering assembly 22 in a manner to be described. The tape-like segment 46 is of a sufficient length to be secured to the positive displacement metering assembly 22.

Intermediate the ends, i.e., between the first end portion adjacent the first end and the second end portion adjacent the other end, the tubular reservoir 40 is filled with a fluid medication such as insulin that is to be discharged into a human

body. The distance between the end portions is of a preselected length and defines therebetween a plurality of courses or loops, such as loops 48 which are finger-like in configuration. Loops 48 may be disposed in a generally coplanar array or, alternatively, may lie as in stacks in a plurality of planes, and preferably, the preselected length is such that at least a week's supply of fluid to be infused is provided.

The positive displacement metering assembly 22 comprises a driven take-up shaft or spool 50. As seen in FIGURES 2 to 4, a typical take-up spool 50 is mounted for rotation with respect to a support 52. Spool 50 defines a slot 54 in which the end of segment 46 is secured and retained. Segment 46 also passes between a pair of squeeze surfaces, such as rotatably-mounted closely spaced squeeze rollers 56. Squeeze rollers 56 are rotatably journalled on a carrier ring 60 which is secured to support 52. Support 52 may form part of the enclosure or housing for the metering assembly.

When take-up spool 50 is driven as by driven gear 58, it is caused to rotate in a counterclockwise direction as seen in FIGURE 2. As it so rotates, the tape-like segment 46 and second end portions move in a direction which reduces the preselected length. As such, the tape-like segment moves between squeeze rollers 56 and is wound upon the adjacent surface of take-up spool 50. When the tape-like segment 46 at the end of the reservoir has completely passed between squeeze rollers 56, the generally circular portion of tubular reservoir 40, i.e., the portion filled with the fluid to be discharged, enters the bight of the squeeze rollers. Because of their closely spaced relationship, the rollers squeeze,

collapse and flatten the wall of the tubular reservoir 40 at the bight thereby tending to increase the pressure in the tubular reservoir, causing fluid to be positively displaced toward the first end portion for discharge through the connector segment 42.

To facilitate the winding and wrapping of the collapsed and flattened portions of the tubular reservoir on the take-up spool 50, cam means are provided to reciprocate the take-up spool with respect to carrier ring 60 and axially of its length, as best illustrated in FIGURES 3 and 4. Regardless of the relative vertical position of the take-up spool and carrier ring, the squeeze rollers continue to act upon the tubular reservoir to collapse and flatten it, thereby continuously and positively to meter and displace the fluid towards the first end portion as the flattened portion of the tubular reservoir is wound upon the take-up spool. Of course, the reciprocation of the take-up spool tends to wind the flattened reservoir portions in a helical or spiral pattern, thereby minimizing the variation in the effective diameter of the take-up spool as more of the flattened tubular reservoir is wound thereon. Carrier ring 60 can also be independently rotatable with respect to shaft 50 so that squeeze rollers 56 can be positioned with respect to tubular reservoir 40 for optimum coaction therewith at any given time during the dispensing cycle.

The driven gear 58 is driven by the power source 26 which preferably includes a conventional motor 61 having a power output for driving a drive gear 62. Drive gear 62 engages driven gear 58 to positively rotate take-up spool 50. The motor may be an electrical motor or it may be a mechanical motor, e.g., a spring-driven mechanism. The motor, hence

the drive gear, is caused to operate either continuously or intermittently in response to microprocessor 24 or to an alternate mechanically activated control mechanism. The control mechanism, such as the microprocessor 24, controllably varies the rate at which the preselected length is reduced and flattened, thereby selectively to vary the rate of displacement of the fluid.

Preferably, microprocessor 24 is a digital logic system for controlling the power source 26, hence the take-up spool 50. Microprocessor 24 may be programmed to provide varying drive rates, whether intermittent or continuous. In that manner, the rate of delivery of fluid displaced towards the first end portion for discharge into the human body may be varied, and supplemental or additional infusions (bolus) of fluid as may be necessary may also be provided for. The microprocessor might also monitor the basal rate of flow as a double check against the programmed dispensing and might also be used to sound an alarm or otherwise provide a signal when the reservoir is almost empty, as in a manner to be pointed out hereinafter.

The details of the necessary logic for the microprocessor are readily apparent to an electronics engineer given the intended functions and accordingly, a detailed schematic is not included in the drawings. Suffice it to say that microprocessor 24 includes a variable pulse generator for driving or operating the motor 61 at variable, selectable rates, and also a secondary, faster pulse generator for providing "bolus" infusions, as in response to the depression of a suitable actuator, such as a push-button by the patient, or as a result of a signal from an implanted blood-sugar sensor if such is used as part of the system.

When used for insulin infusion, the positive displacement metering assembly 22 provides for rotating the take-up spool at a rate such that the squeeze rollers collapse the tubular reservoir sufficiently to positively displace the insulin solution towards the first end portion at a rate of from about 0.000533 ml. per minute to 0.0025375 ml. per minute.

Of course, the rate at which the take-up spool rotates will depend upon the internal diameter of the reservoir 40 or, in other words, upon the volume of insulin contained per unit length of the tubular reservoir, and the rate of rotation will be easily determined by the designer. The indicated rates provide a total volume delivered for a twenty-four hour period between a minimum of about 0.4872 ml. to a maximum of about 3.654 ml. These values are based upon an insulin dilution of 1:9. At this dilution the rate of insulin infusion is between about 0.04872 and 0.3654 ml. for a twenty-four hour period which corresponds to about 0.2 to 1.5 units of insulin per hour. The rate of infusion can be adjusted, or even increased beyond the indicated amounts when so prescribed by a physician.

The secondary, faster pulse generator may increase the infusion rate for a predetermined period by increasing the speed of the drive gear 62, hence the speed of rotation of the take-up spool for a preselected time period.

The entire metering assembly 22 may be disposed in a housing 64 which is removably connected to the enclosure 30. In that instance, the tape-like end segment 46 will be suitably threaded with respect to the squeeze rollers and take-up spool and wound sufficiently so that the reservoir is ready for

discharging upon actuation. Alternatively, the metering assembly housing may coincide with the enclosure 30, with the end segment 46 being pre-threaded and the entire reservoir-metering assembly made available as a replaceable unit. In either case, the power source and motor may be associated with or separate from the metering assembly, but preferably is part of the metering assembly so that all that is necessary for actuating the system is to "plug in" the power supply, if the motor is an electrical motor, and the microprocessor which programs the application of power from the power supply.

Referring again to the discharge end of the tubular reservoir 40, the connector segment 42 is suitably secured to the cannula segment 43 and needle 28 to provide the necessary sterility and for insertion of the needle 28 subcutaneously in a known manner. Alternatively, connector segment 42 and a cannula segment 43 may be configured and provided with a needle adapted to cooperate with a puncturable septum in an associated catheter, as in the manner disclosed and described in commonly owned copending application Serial No. 072,264, filed on September 4, 1979. Such needles may be provided with a protective cap or sheath, as desired.

As has been pointed out, referring again to FIGURE 2, the tubular reservoir 40 is readily replaceable and preferably is disposed in a housing or enclosure 30. The housing 30 may also contain the positive displacement metering assembly 22, although it may be a reusable separate subassembly securable to the reservoir enclosure 30. If housed together in a replaceable unit, to use the reservoir-metering assembly 22, it is merely necessary to connect the

unit to the power supply 26 and microprocessor 24 at one end, and the connector segment and cannula segment to the infusion means at the other end, and the reverse is undertaken when the insulin supply in the reservoir has been depleted. To indicate that the supply is nearing depletion, it may be desirable to provide a signal. One such signalling means may comprise colored or other visible portions on the tubular reservoir which signify 12 hours, 6 hours and 3 hours of supply remaining, respectively, and which are viewable through a window 70 adjacent the take-up spool. Alternatively, an end portion of the tubing may be provided with a conductive material, such as a conductive metal coating in the form of a band or bands, which, as it is taken up on the take-up spool, is sensed, as by a proximity sensor associated with the microprocessor, which in turn audibly or visibly signals that the supply remaining is sufficient for say three hours. The signalling means may comprise markings like those used on common insulin syringes or magnetically encoded markings readable by a user or by a sensor.

The embodiment of FIGURE 5 is similar in most respect to that of FIGURES 1 to 4. Its principal differences are in the disposition of the loops of the tubular reservoir and in the support for the metering means.

As seen in FIGURE 5, the tubular reservoir 140 has a fan-like disposition in plan view. Reservoir 140 has a plurality of loops 148 which are finger-like in configuration and has a connector 142 and a cannula segment 143 terminating in a needle 128 at one end portion and a sealed, tape-like segment 146 at the other end. The tape-like segment is adapted to be threaded between squeeze rollers 156

and to be received in a tape receiving slot 154 in a take-up spool 150 in the same manner described in connection with FIGURES 1 to 4. The take-up spool is driven in the same manner as described previously.

However, the entire positive displacement metering means in this instance is mounted on a carrier 160 which is mounted on tracks 172. Tracks 172 are secured to the enclosure 130 housing the reservoir 140. After substantially all of the tubular reservoir 140 has been wrapped upon the take-up spool 150, the carrier 160 will be caused to be drawn along tracks 172 so that substantially the entire length of the tubular reservoir 140 may be collapsed for discharge through the tubular connector segment 142, hence into an associated cannula or catheter and into the associated human body.

Referring now to FIGURES 6 and 7, a further embodiment of the present invention is there shown. Again, it is similar in most respects to the embodiment of FIGURES 1 to 4. There a tubular insulin reservoir 240 is provided. It has a sealed tape like segment 246 at one end and a tubular connector segment 242 at the other end. The reservoir 240 comprises a plurality of loops 248 which are generally circular in plan view, most of which may lie in a single plane. The metering assembly comprises a take-up spool 250 and a pair of squeeze roolers 256, and these are mounted, function and cooperate with the tubular reservoir 240 in the same manner in which the take-up spool and squeeze rollers cooperate with the tubular reservoir 40 in the embodiment of FIGURES 1 to 4.

In the embodiment of FIGURES 6 and 7, the loops of the coil are spirally or helically disposed in plan view. As seen in side view in FIGURE 6, at

least one of the loops is in a plane different from the other loops so that, as the take-up spool nears the end of the tubular reservoir 240, it will not kink. It is also preferable in this embodiment that a slide guide 257 be positioned adjacent the take-up spool and squeeze rollers, thereby to permit the loops to slide past the take-up spool 250 and squeeze rollers 256 without being acted upon by them prior to their being drawn into the bight of the squeeze rollers 256.

In the embodiment of FIGURE 8, a single squeeze roller 356 is provided. It cooperates with take-up spool 350 to provide a pair of squeeze surfaces to squeeze a tubular reservoir 340 therebetween. The squeeze roller 356 and take-up spool 350 serve both to take up the end of the tubular reservoir and to wind the tubular reservoir 340 on the take-up spool, and to collapse and flatten the tubular reservoir, as did the pairs of squeeze rollers shown in the embodiments of FIGURES 1-7.

The tubular reservoir illustrated in the embodiments of FIGURES 1-8 were described as being generally circular in cross section. However, tubular reservoirs having other cross-sections may be used and in FIGURE 9, a generally elliptical tubular reservoir 440 is illustrated. It too is of a dimensionally stable, sterile and sanitary material.

Although the positive displacement metering assemblies described so far incorporate a driven take-up shaft or spool, it is also possible to drive squeeze rollers instead of, or in addition to, the take-up spool. As seen in FIGURE 10, a fragmentary metering assembly is seen to comprise a pair of spaced apart squeeze rollers 456 and a take-up spool 450. Each roller has a knurled surface to grippingly

engage a tubular reservoir to compress and flatten the same and positively to pull the flattened portion through the bight. Rollers 456 are driven via gears 471, which in turn are driven by a motor drive gear 462. Motor drive gear is 462 is controlled by a suitable power source and controller, such as a microprocessor, as previously described.

Motor drive gear 462 may directly engage gears 471 or may engage a further gear means 480 to drive gears 471. It may also drive take-up spool gear 481 which is preferably provided with a slip-clutch so that the take-up spool 450 may suitably wind up the flattened reservoir portions, as in the manner previously described, but without influencing the rate at which the reservoir is drawn between the squeeze rollers. In the embodiment of FIGURE 10, the rate at which the reservoir is flattened, hence dispenses and meters, is controlled by the squeeze rollers and is not potentially influenced by any increase in the diameter of the take-up spool occasioned by the wrapping of the flattened reservoir portions thereon. In the embodiment of FIGURE 10, the take-up spool is not mounted for reciprocation because any effective increase in spool diameter does not influence the rate at which the fluid medication is metered.

Referring to FIGURE 11, the further reservoir 540 may terminate in a connector section including a reduced diameter cannula segment 543 and a retainer means such as connector bead 542. Pull-out of the needle 528 associated with cannula segment 543 is prevented by the cooperation between segment 543 and the associated housing 530. Thus, in this embodiment, the connector means is integral with the reservoir and provides both a direct connection

between the reservoir and needle and also provides the means for anchoring to the housing so that pull-out does not occur. The assembly may otherwise be the same as that of FIGURES 1 to 4.

The foregoing description and the drawings are intended as illustrative and are not to be taken as limiting. Still other variations and rearrangements of parts within the spirit and scope of this invention are possible and will be readily apparent to those skilled in the art who are familiar with the foregoing description and drawings.

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WHAT IS CLAIMED IS:

1. A system for controllably delivering fluid at selected rates for discharge into a human body, which comprises

an elongate, continuous thin-walled tubular reservoir having a first end portion and a connector means adjacent a first end, and a second end portion adjacent the other end, said reservoir being filled with a fluid between said end portions and having a preselected length between said end portions;

the connector means at said first end portion being adapted to be placed in fluid communication with means for discharging fluid into a human body; and

a powered positive displacement metering assembly adjacent said second end portion for moving said second end portion in a direction to reduce said preselected length and for flattening said tubular reservoir as it moves in said direction, thereby positively to displace said fluid toward said first end portion to force said fluid toward said means for discharging said fluid into a human body.

2. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 1 wherein said connector means comprises a cannula extending from said first end portion and terminating in said fluid discharge means.

3. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 2 wherein said fluid discharging means comprises a needle.

4. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 1 wherein said

thin-walled tubular reservoir defines a plurality of loops between said first and second end portions.

5. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 4 wherein a plurality of said loops are generally coplanar.

6. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 4 wherein said loops are of a generally zig-zag configuration.

7. A system for controllably delivering fluid at selected rates of discharge into a human body in accordance with claim 5 wherein said loops are generally finger-like in configuration.

8. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 4 wherein said loops are generally circular in configuration.

9. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 8 wherein said generally circular loops comprise a continuous coil.

10. a system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 8 wherein a plurality of said loops lie generally in a single plane.

11. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 1 wherein said powered positive displacement metering assembly includes a pair of closely spaced squeeze surfaces for flattening said tubular reservoir to displace fluid toward said first end portion.

12. A system for controllably delivering fluid at selected rates for discharge into a human

body in accordance with claim 11 wherein said squeeze surfaces comprise squeeze rollers.

13. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 12 further including means for driving said squeeze rollers at selectable rates.

14. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 1 wherein said powered positive displacement metering assembly comprises a motor means and a take-up spool driven by said motor means for winding said tubular reservoir thereon as said preselected length is reduced and flattened.

15. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 14 wherein said metering means further comprises squeezing means associated with said take-up spool for flattening said tubular reservoir to displace fluid toward said first end portion.

16. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 15 wherein said squeezing means comprises a pair of squeeze surfaces adjacent said take-up spool.

17. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 16 wherein said squeeze surfaces are rollers and wherein said motor means is further connected to said squeeze rollers to drive both said rollers and said take-up spool.

18. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 16 wherein said squeeze

surfaces are mounted on a carrier, and further comprising means mounting said take-up spool for movement axially of said carrier.

19. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 11 wherein said thin-walled tubular reservoir defines a plurality of loops between said first and second end portions.

20. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 1 further comprising means for selectively controlling the positive displacement metering assembly thereby controllably to vary the rate at which said preselected length is reduced and flattened, thereby selectively to vary the rate at which fluid is displaced toward said first end portion.

21. A replaceable cartridge for use in a system for controllably delivering fluid at selected rates for discharge into a human body, said cartridge comprising

an enclosure,

an elongate, continuous, readily flattenable thin-walled tubular reservoir in said enclosure and having a first end portion and a connector means adjacent a first end and a second end portion adjacent the other end, said reservoir being filled with a fluid between said end portions and having a preselected length between said end portions, and

said connector means being secured to said enclosure at said first end portion, said connector means being adapted to be placed in fluid communication with means for discharging said fluid into a human body, and

said second end portion defining a segment adapted to be secured to a driven metering assembly for reducing and flattening said preselected length at a predetermined rate positively to displace and meter fluid through said connector means.

22. A replaceable cartridge for a system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 21 wherein said thin-walled tubular reservoir defines a plurality of loops between said first and second end portions.

23. A replaceable cartridge for a system for controllably delivering fluid at selected rates of discharge into a human body in accordance with claim 22 wherein said loops are generally finger-like in configuration.

24. A replaceable cartridge for a system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 22 wherein said loops are generally circular in configuration.

25. A replaceable cartridge for a system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 22 further comprising a driven metering assembly supported on said enclosure, said assembly including closely spaced squeeze surfaces for flattening said tubular reservoir to displace fluid toward said first end portion, and means for connecting said driven metering assembly to a power supply.

26. A replaceable cartridge for a system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 25 wherein said squeeze surfaces comprise a pair of squeeze rollers.

27. A replaceable cartridge for a system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 26 wherein said metering assembly further comprises a take-up spool for winding said tubular reservoir thereon as said preselected length is reduced and flattened.

28. A replaceable cartridge for a system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 27 wherein said squeeze rollers are mounted on a carrier, and means mounting said take-up spool for movement axially of said carrier to promote helical winding of said flattened tubular reservoir on said take-up spool.

29. A system for controllably delivering fluid at selected rates for discharge into a human body, comprising

a replaceable enclosure,

an elongate, continuous, readily flattenable thin-walled tubular reservoir in said enclosure and having a first end portion adjacent a first end and a second end portion adjacent the other end, said reservoir being filled with a fluid between said end portions and having a preselected length between said end portions, said reservoir having a connector means secured to said enclosure at said first end portion, said connector means being adapted to be placed in fluid communication with means for dis- charging said fluid into a human body,

said second end portion defining a segment adapted to be secured to a metering assembly,

a positive displacement metering assembly adjacent said second end portion for securing and moving said second end portion in a direction to

reduce said preselected length and for flattening said tubular reservoir as it moves in said direction, thereby positively to displace fluid toward said first end portion to force fluid through said connector means toward said means for discharging said fluid into a human body, and

a power source for operating said metering assembly.

30. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 29 wherein said thin-walled tubular reservoir defines a plurality of loops between said first and second end portions.

31. A system for controllably delivering fluid at selected rates of discharge into a human body in accordance with claim 30 wherein said loops are generally finger-like in configuration.

32. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 30 wherein said positive displacement metering assembly includes closely spaced squeeze surfaces for flattening said tubular reservoir to displace fluid toward said first end portion.

33. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 32 wherein said positive displacement metering assembly comprises a take-up spool driven by said power source for winding said tubular reservoir thereon as said preselected length is reduced and flattened.

34. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 33 wherein said metering assembly comprises said take-up spool, and said

squeeze surfaces comprise a pair of closely spaced squeeze rollers adjacent said take-up spool.

35. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 34 wherein said squeeze rollers are mounted on a carrier, and further comprising means mounting said take-up spool for movement axially of said carrier.

36. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 29 further comprising a controller for selectively controlling the power source thereby controllably to vary the rate of movement of said tubular reservoir and the rate at which said preselected length is reduced and flattened, thereby selectively to vary the rate at which fluid is displaced toward said first end portion.

37. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 29 wherein said positive displacement metering assembly is mounted on said replaceable enclosure.

38. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 29 wherein said metering assembly is in said enclosure and said second end portion segment is secured to said metering assembly.

AMENDED CLAIMS
(received by the International Bureau on 25 May 1981 (25.05.81))

1. A system for controllably delivering fluid at selected rates for discharge into a human body, which comprises

an elongate, continuous thin-walled tubular reservoir having a first end portion and a connector means adjacent a first end, and a second end portion adjacent the other end, said reservoir being filled with a fluid between said end portions and having a preselected length between said end portions;

the connector means at said first end portion being adapted to be placed in fluid communication with means for discharging fluid into a human body; and

a powered positive displacement metering assembly adjacent said second end portion, said metering assembly including a motor driven take-up spool for moving said second end portion in a direction to reduce said preselected length and means for flattening said tubular reservoir as it moves in said direction, thereby to positively displace said fluid toward said first end portion to force said fluid toward said means for discharging said fluid into a human body.

2. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 1 wherein said connector means comprises a cannula extending from said first end portion and terminating in said fluid discharge means.

3. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 2 wherein said fluid discharging means comprises a needle.

4. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 1 wherein said thin-walled tubular reservoir defines a plurality of loops between said first and second end portions.

5. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 4 wherein a plurality of said loops are generally coplanar.

6. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 4 wherein said loops are of a generally zig-zag configuration.

7. A system for controllably delivering fluid at selected rates of discharge into a human body in accordance with claim 5 wherein said loops are generally finger-like in configuration.

8. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 4 wherein said loops are generally circular in configuration.

9. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 8 wherein said generally circular loops comprise a continuous coil.

10. a system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 8 wherein a plurality of said loops lie generally in a single plane.

11. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 1 wherein said means for flattening said tubular reservoir includes a pair of closely spaced squeeze surfaces for flattening said tubular reservoir to displace fluid toward said first end portion.

12. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 11 wherein said squeeze surfaces comprise squeeze rollers.

13. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 12 further including means for driving said squeeze rollers at selectable rates.

14. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 11 wherein said squeeze surfaces are positioned adjacent said take-up spool.

15. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 14 wherein said squeeze surfaces are rollers and wherein said motor means is further connected to said squeeze rollers to drive both said rollers and said take-up spool.

16. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 14 wherein said squeeze surfaces are mounted on a carrier, and further comprising means mounting said take-up spool for movement axially of said carrier.

17. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 11 wherein said thin-walled tubular reservoir defines a plurality of loops between said first and second end portions.

18. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 1 further comprising means for selectively controlling the positive displacement metering assembly thereby controllably to

vary the rate at which said preselected length is reduced and flattened, thereby selectively to vary the rate at which fluid is displaced toward said first end portion.

19. A system for controllably delivering fluid at selected rates for discharge into a human body, comprising

a replaceable enclosure,

an elongate, continuous, readily flattenable thin-walled tubular reservoir in said enclosure and having a first end portion adjacent a first end and a second end portion adjacent the other end, said reservoir being filled with a fluid between said end portions and having a preselected length between said end portions, said reservoir having a connector means secured to said enclosure at said first end portion, said connector means being adapted to be placed in fluid communication with means for dis- charging said fluid into a human body,

said second end portion defining a segment adapted to be secured to a metering assembly,

a positive displacement metering assembly adjacent said second end portion, said metering assembly including a take-up spool for securing and moving said second end portion in a direction to reduce said preselected length and means for flattening said tubular reservoir as it moves in said direction, thereby positively to displace fluid toward said first end portion to force fluid through said connector means toward said means for discharging said fluid into a human body, and

a power source for operating said metering assembly.

20. A system for controllably delivering fluid at selected rates for discharge into a human

body in accordance with claim 19 wherein said thin-walled tubular reservoir defines a plurality of loops between said first and second end portions.

21. A system for controllably delivering fluid at selected rates of discharge into a human body in accordance with claim 20 wherein said loops are generally finger-like in configuration.

22. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 20 wherein said means for flattening said tubular reservoir includes closely spaced squeeze surfaces for flattening said tubular reservoir to displace fluid toward said first end portion.

23. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 22 wherein said metering assembly comprises said take-up spool, and said squeeze surfaces comprise a pair of closely spaced squeeze rollers adjacent said take-up spool.

24. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 23 wherein said squeeze rollers are mounted on a carrier, and further comprising means mounting said take-up spool for movement axially of said carrier.

25. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 19 further comprising a controller for selectively controlling the power source thereby controllably to vary the rate of movement of said tubular reservoir and the rate at which said preselected length is reduced and flattened, thereby selectively to vary the rate at which fluid is displaced toward said first end portion.

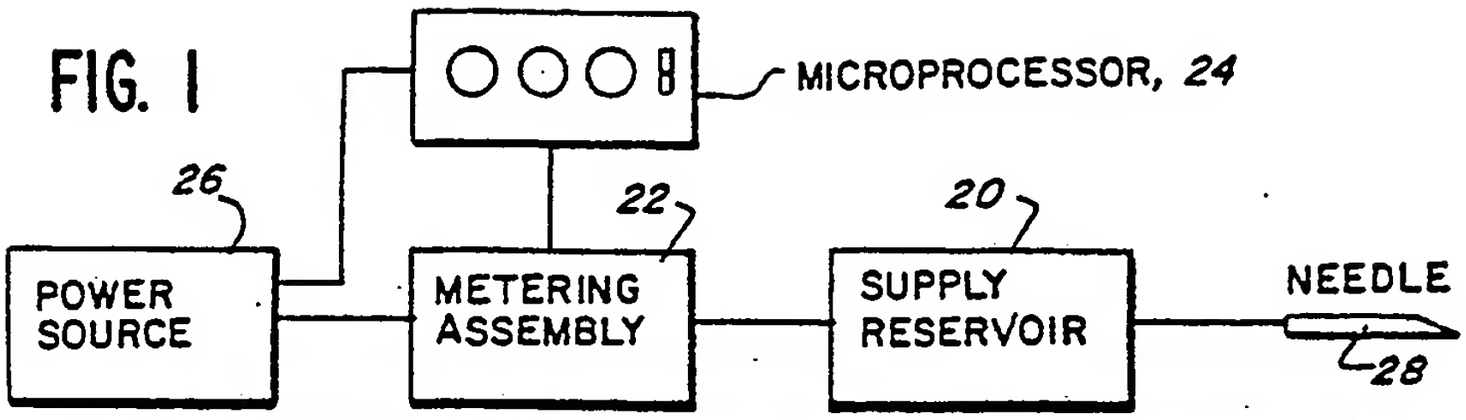
26. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 19 wherein said positive displacement metering assembly is mounted on said replaceable enclosure.

27. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 19 wherein said metering assembly is in said enclosure and said second end portion segment is secured to said metering assembly.

## STATEMENT UNDER ARTICLE 19

The amendments have been made to conform the PCT application to the claims that presently exist before the United States Patent and Trademark Office. Previous claims 14, 15, 21-28 and 33 have been deleted. The remaining claims have been renumbered accordingly. New claims 1, 11, 14, 19 and 22 have been amended to further define the invention. Support for all of these amendments can be found in the specification, deleted claims, and the drawings.

FIG. 1



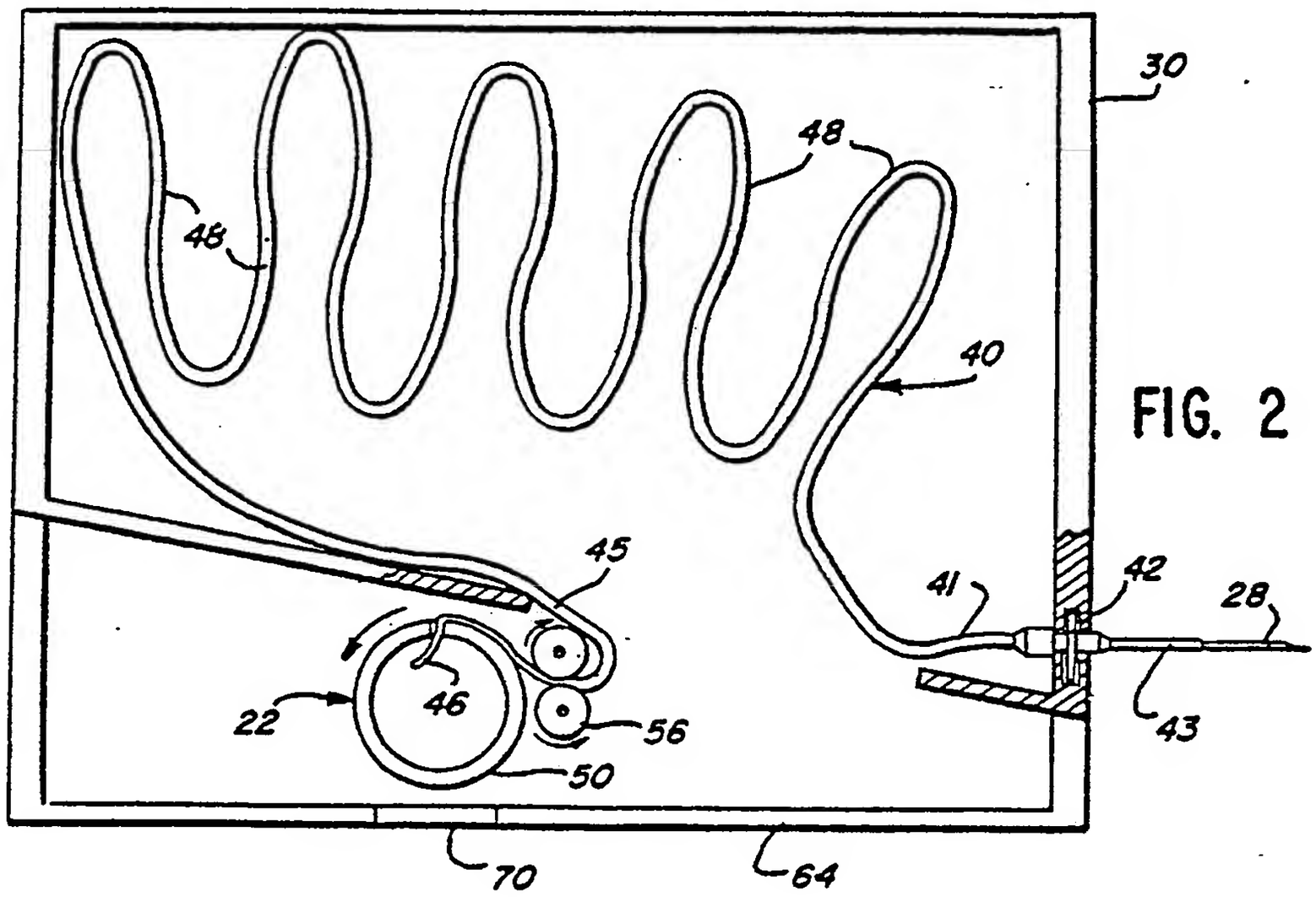




FIG. 2

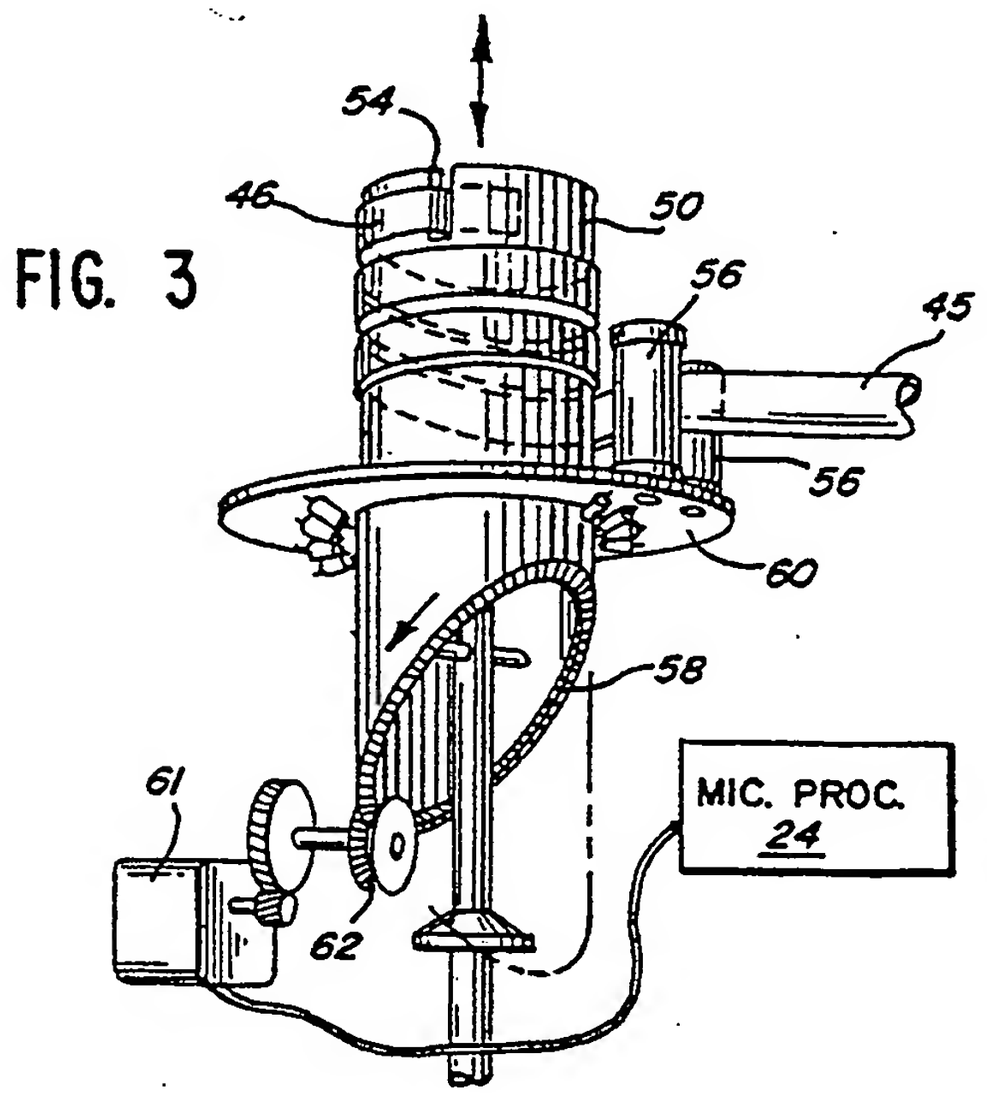



FIG. 3

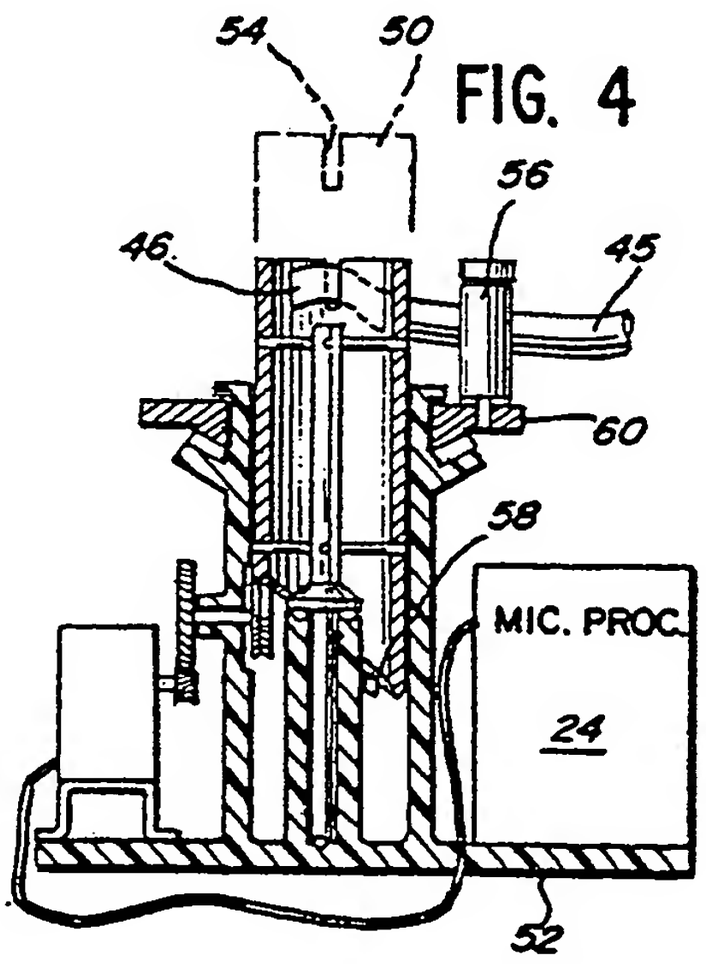



FIG. 4

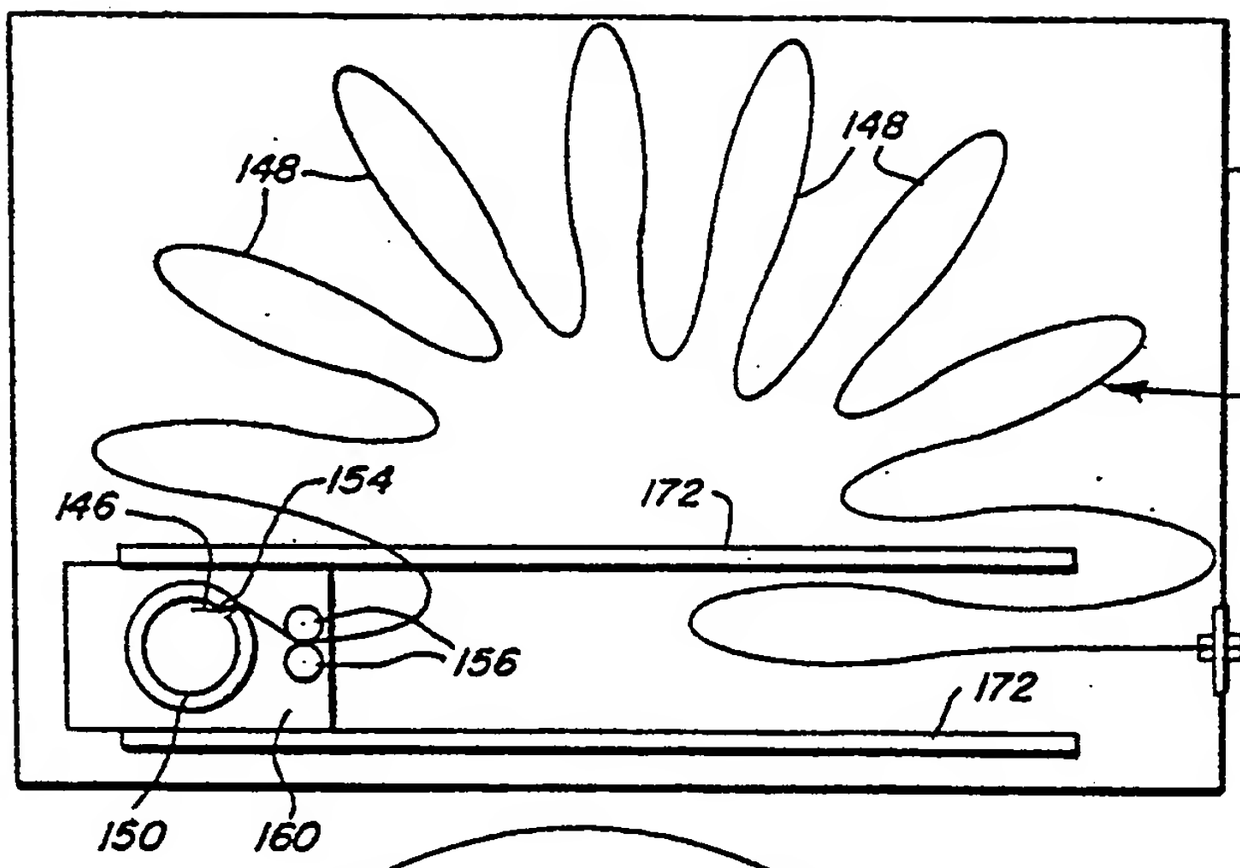



FIG. 5

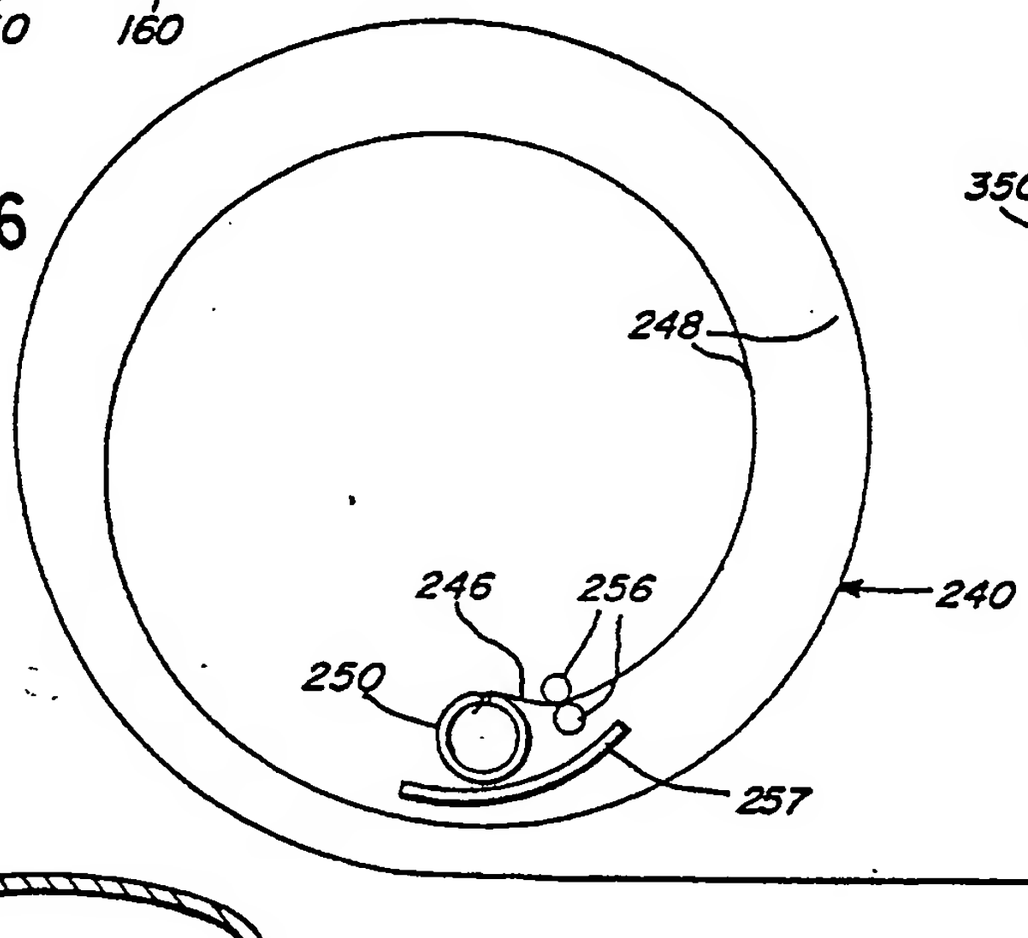



FIG. 6

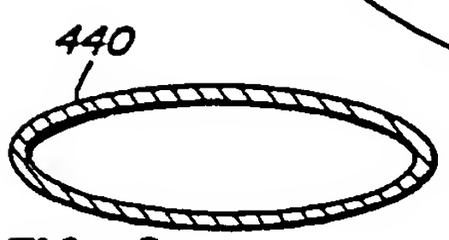



FIG. 9




FIG. 7

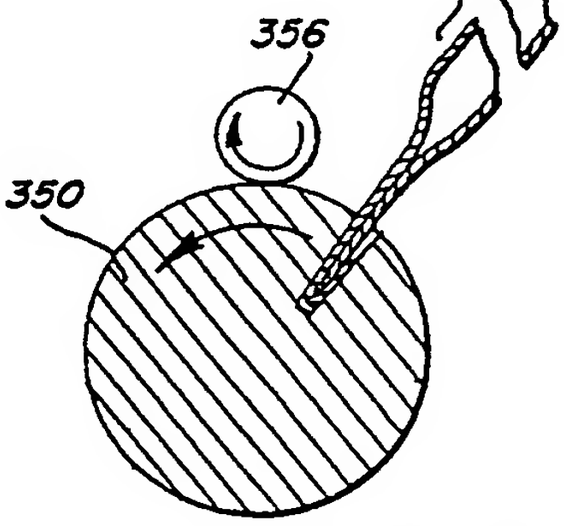
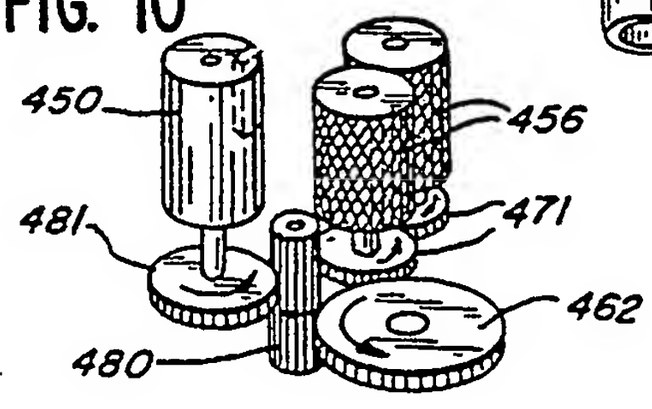



FIG. 8

FIG. 10



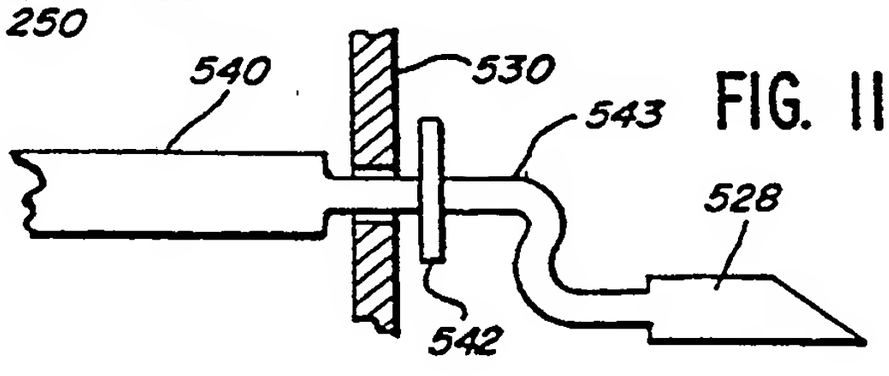




FIG. 11

# INTERNATIONAL SEARCH REPORT

International Application No PCT/US80/01630

## I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl. A61M 5/14
U.S. Cl. 128/214

## II. FIELDS SEARCHED

Minimum Documentation Searched [4]

| Classification System | Classification Symbols |
|---|---|
| U.S. | 128/214R 214E 214F; 242/86 67.2; 222/102 209 |

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

## III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

| Category * | Citation of Document, [16] with indication, where appropriate, of the relevant passages [17] | Relevant to Claim No. [18] |
|---|---|---|
| X | GB, 862,872, Published 15 March 1961 | 1-38 |
| X | IT, 482,243, Published 25 June 1953 | 1,16-18 26-28,32-35 |
| X | US,A, 3,198,385, Published 03 August 1965 | 1-3,11-13, 20,32,36 |
| X | US,A, 3327898 Published 27 June 1967 | 4-10,21-23, 25,31 |
| X | US,A, 3,471,885, Published 14 October 1969 | 14-16,18,29 33-35 |

* Special categories of cited documents: [15]

"A" document defining the general state of the art

"E" earlier document but published on or after the international filing date

"L" document cited for special reason other than those referred to in the other categories

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but on or after the priority date claimed

"T" later document published on or after the international filing date or priority date and not in conflict with the application, but cited to understand the principle or theory underlying the invention

"X" document of particular relevance

## IV. CERTIFICATION

| Date of the Actual Completion of the International Search [2] | Date of Mailing of this International Search Report [2] |
|---|---|
| 16 March 1981 | 24 MAR 1981 |
| **International Searching Authority [1]** | **Signature of Authorized Officer [20]** |
| ISA/US | R. Mitchell |